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EXAMINER
DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,196	LEBEL ET AL.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 6-9, 12-16, 18, 19, and 22-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Causey, III et al. (USPN 6,641,533).

Causey, III et al. discloses a MD electronic control circuitry, that further comprises at least one MD telemetry system, and at least one MD processor that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system (Figures 2, 5, 7, 22, 24 and entire reference).

3. Claims 12 – 14, are rejected under 35 U.S.C. 102(e) as being anticipated by Saltzstein et al. (USPN 5,931,791).

Saltzstein et al. discloses a MD electronic control circuitry, that further comprises at least one MD telemetry system, and at least one MD processor that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system (Figures 1-6 and entire reference).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 6 - 10, and 12 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al. USPN 5,630,710, and further in view of Goedeke (USPN 5,904,708).

Tune et al. discloses a medical system, comprising an ambulatory medical device (MD) [Ref. # 10] comprising MD electronic control circuitry (546) that further comprises at least one MD telemetry system (562, 564, 566) and at least one MD processor (542) that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) [Ref. # 952] comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system, wherein the medical device is comprises an infusion pump (10), and wherein the CD display device is controlled to show a plurality of infusion parameters simultaneously, and wherein a first portion of the MD telemetry system is incorporated into the MD processor and a second portion of the MD telemetry system is external to the MD processor, or wherein a first portion of the CD telemetry system is incorporated into the CD processor and a second portion of the CD telemetry system is external to the CD processor, wherein (1) the MD electronic

control circuitry comprises at least one external MD functional module, other than the second portion of the MD telemetry system, that is external to the MD processor, (2) the CD electronic control circuitry comprises at least one external CD functional module, other than the second portion of the CD telemetry system, that is external to the CD processor, (3) the MD processor comprises an internal MD CPU and at least one other internal MD functional module, or (4) the CD processor comprises an internal CD CPU and at least one other internal CD functional module. (Figures 2,25-30,32-41, and entire reference).

Tune et al. also discloses the communication device with a CD display controlled by at least one CD processor for providing visual feedback to the patient, and wherein the feedback comprises a display of the quantity of a consumable estimated to be remaining in the system (512), wherein the consumable is a drug, and where the medical device wherein infusion parameters can be selected, and where the patient can program (28) there own options into the pump. (Column 3, lines 29-47), but fails to disclose wherein the telemetry device uses RF signals.

Goedeke discloses the use of an implantable pump with telemetry components, wherein the telemetry used is RF telemetry.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Tune et al. with the teachings of Goedeke because it is well known to use RF telemetry with implantable medical devices or any medical devices that communicate, through telemetry, as stated in the entire reference of Goedeke (See Column 1, lines 40 to Column 2, line 6, as well as entire reference).

Therefore, it would have been obvious to combine Tune et al. with Goedeke to obtain the invention as specified in claims 6-10, and 12-15.

4. Claims 6-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. (USPN 6,641,533).

Causey, III et al. discloses the claimed invention but fails to disclose a display screen that displays the drug estimated to be remaining in a reservoir, the batter power remaining, the time-of-day indicator and finally the battery indicator.

At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the disclosed invention of Causey, III et al. to include these display options because it is well known in the medical field and pump art to incorporate these options when dealing with a display on a pump and/or remote device controlling the pump to make the overall operating procedure by the patient or medical personnel easier. (This can be seen in the other references used in the office action [Tune et al., Goedeke, and Er])

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al. with Goedeke as applied to the claims above, and further in view of Er (USPN 6185461).

Tune et al. in combination with Goedeke disclosed the claimed invention except wherein the consumable is either (1) battery power remained in a replaceable CD battery in the communication device and a voltage level on the CD battery is graphically depicted with a desired resolution, or (2) battery power remaining in an MD battery in

the medical device and a voltage level on the battery is graphically depicted with a desired resolution.

Er discloses a controlled system where the display, displays the battery data and battery longevity estimate graph (Figure 1 and 2 and entire reference).

At the time of the invention, it would have been obvious for a person with ordinary skill in the art to combine Tune et al. and Goedeke medical infusion device with Er replacement time indicator device and display, because according to Er, it is highly desirable to predict when a battery will failure so as to make arrangements for the replacement battery. (Column 2, lines 1-9).

Response to Arguments

6. Applicant's arguments with respect to claims 6-28 have been considered but are not persuasive.

7. The applicant argues one point, and that is that none of the prior art: discloses a CD device that enables or disables at least one patient programmable option. The applicant argues that the prior art does not teach a CD display that displays a patient's programmable options wherein the option may be enabled or disabled. The examiner disagrees with the applicant because Causey III, et al. discloses that feature in Column 11, lines 28-48,as well as in Column 14, lines 8-37. The examiner would also like to note that the claims read as the patient option "**MAY BE ENABLED** or disabled". Therefore, the examiner interprets that as an option that has the ability to be enabled, but does not need to be enabled. Also the examiner would like to note that the claim does have to be disabled because of the term "or".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
September 20, 2004

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